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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,265	08/07/2006	Michael Mittelstein	NEOME-019A2US	3349

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	**PAPER NUMBER**
3739	

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11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,265	MITTELSTEIN ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-25 and 27-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-25 and 27-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/9/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2009 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of these claims recite “A device” in the preamble, but depend from a system claim. The preamble of each claim should be amended to be commensurate with the independent claim from which it depends. Additionally, claim 24 lacks clear antecedent basis for "the endoscopic device".

Claim Rejections - 35 USC § 102

Claims 1, 6-9, 11, 14-19, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Haissaguerre et al (6,086,629).

Haissaguerre et al disclose a device for cutting or coagulating tissue comprising an elongate member (28) having a distal end, and a right foot member (36) and a left foot member (34) extending angularly from the distal end of the elongate member (see Figure 1). Each foot member includes an upper surface and a lower surface with an electrode located on the upper surface of each foot member (see Figure 6). An electrically and thermally insulating covering (108,110) is formed on each foot member, particularly covering the lower surface and part of the top surface (see Figure 6). There is a space between the foot members (Figure 6) and the electrodes are used to treat tissue located above the open space. The electrodes are connected to an RF energy source, and the foot members are part of a bifurcated member (i.e. the entire distal tip) extending from the distal end of the catheter. It is noted that Haissaguerre et al disclose embodiments whereby the electrodes extend directly from the elongate member in a bifurcated fashion (figures 19-21). Regarding claim 8, the electrodes are located on top of the insulating covering (see Figure 6), and Haissaguerre et al disclose lumens (85,87) for providing fluid to the electrodes (col. 8, lines 23-30).

Applicant's claim 14 is drawn to a product-by-process claim and the structure of Haissaguerre et al is deemed to meet the structure of the product. The process by which the structure is made does not patentably distinguish over the Haissaguerre et al reference. See MPEP 2113.

Regarding claims 15-19, Haissaguerre et al clearly disclose a handle (4 – Figure 1), from which the elongate member extends. The device is inherently deemed separable such that the elongate member is releasably attached to the handpiece. It is

noted there is no structure associated with this broad recitation of a releasable relationship. The handpiece and elongate member are also deemed inherently autoclavable. There is no requirement that they need be functional after such a treatment, nor any limitation describing the autoclavable nature such that they may be reused.

The method of using the Haissaguerre et al device to treat tissue is fully disclosed throughout the specification and the drawings.

Claim Rejections - 35 USC § 103

Claims 10, 12, 13 and 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629) in view of the teaching of Jahns et al (2002/0002372).

Regarding claim 10, as noted above, Haissaguerre et al disclose a lumen for providing a fluid to tissue. however, there is no disclosure of another lumen for aspirating fluid.

Jahns et al, as addressed in the previous Office action, teach that it is generally known to provide RF electrode devices with lumens for providing aspiration and fluid delivery to irrigate the electrode and remove unwanted fluids and debris (paragraphs 0040-0045). Regarding claims 12 and 13, Jahns et al also disclose a wide variety of materials used making/coating the electrosurgical device (paragraphs 0034, 0039, 0065 and 0066). The examiner maintains that the use of any well known polymer material as the insulative portion of a medical device would be an obvious design consideration.

Regarding claim 29-39, Haissaguerre et al disclose uses of the device to treat cardiac tissue. Jahns et al disclose a similar device for treating cardiac tissue, and also disclose alternative uses such as the treatment of kidney, liver, lung, skin and muscle tissue (para. 0031). The examiner maintains that one of ordinary skill in the art would recognize the wide variety of tissue on which an RF device may be utilized. Moreover, applicant's specification discloses a wide array of uses with no criticality or unexpected result associated with any particular use. The use of an RF device to treat any desired tissue is deemed an obvious consideration for the skilled artisan.

To have provided the Haissaguerre et al device with an aspiration lumen for removing fluid and debris from the treatment site would have been an obvious modification for one of ordinary skill in the art, particularly since Jahns et al fairly teach that it is known to provide RF devices with both irrigation and aspiration capabilities. Further, to have formed the Haissaguerre et al device using any well known polymers for the insulative portions is deemed an obvious design consideration, and use of the device to treat any desired tissue site is deemed obvious as asserted in the paragraph above.

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629).

As asserted above, Haissaguerre et al disclose a handle associated with the elongate member. The examiner maintains that any handle member may be deemed "releasably attached" to a catheter portion such as shown by Haissaguerre et al. Again,

there is no recitation of the structure for such a releasable attachment. However, the examiner also maintains that it is generally well-known in the art to provide devices as either integral components or as discrete elements that may be readily separated for cleaning and/or reuse. Such a modification is deemed an obvious design expedient and is well documented throughout the art. There is no disclosure of a novel connection between the components, only that they may be separable as is generally known in the medical field. As such, making the Haissaguerre et al device as an integral, single body device or as a multiple component device that may be readily disassembled and reassembled is deemed an obvious design selection that would be well within the purview of the skilled artisan.

Claims 20-24 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629) in view of the teaching of Underwood et al (6,293,961).

Haissaguerre et al fail to disclose a cannula and/or endoscope components that may be used to introduce the device into the body. The examiner maintains that it is generally well-known to use endoscopes (and/or cannulas) for introducing devices in a minimally invasive procedure. To that end, Underwood et al disclose an alternative RF electrode device, and specifically teach that the device may be provided to a treatment site using endoscopic guidance (Figure 17).

To have provided the Haissaguerre et al device with an endoscope or cannula to facilitate entry of the device to a desired internal tissue area would have been an obvious consideration for one of ordinary skill in the art, particularly since Underwood et

al fairly disclose the known use of an endoscope to provide a similar RF device to treatment sites.

Response to Arguments

Applicant's arguments filed November 13, 2009 have been fully considered but they are not persuasive.

Independent claims 1 and 25 have been amended to recite right and left foot members that extend angularly from the elongate member “and to one side of the elongate member”. Applicant's arguments are centered mostly on the assertion that the Haissaguerre et al device cannot have foot members that extend angularly to “one same side of the shaft" (page 11 of the response).

Initially, it is noted that applicant’s have in no way defined a "side" of the elongate member, in particular with respect to any dimension and/or location. Also, the claims do not recite foot members on “one same side of the shaft” as argued by applicant on pages 11 and 13 of the response. Rather, the claims merely recite the foot members extend angularly "to one side of the elongate member". As such, it is reasonable to assert that the elongate member has two sides: a delivery side which extends up to the distal end of the elongate member, and a treatment side which is distal to the elongate member. With such an interpretation, it is further reasonable to say the foot members extend angularly to one side of the elongate member, specifically to the distal or treatment side such that the treatment electrodes are facing the treatment side.

Applicant also argues that Haissaguerre fails to disclose an open space formed between right and left foot members to treat tissue in the open space. The examiner disagrees. This argument is premised solely on the intended use of the device. While Haissaguerre preferably show the foot members in a fully deployed position with the foot members extending orthogonal to the elongate axis of the elongate member, it is not required that they be fully deployed for operation of the device. That is, the foot members may be partially deployed to treat tissue having an apex such that the foot members would be deployed at an angle having an open space therebetween. That Haissaguerre disclose the device for creating linear lesions does not preclude its use to treat tissue with the foot members partially deployed. Such a deployment may still make use of the entire length of the ablation segment for treating tissue.

Applicant's arguments regarding the obviousness rejections are premised on the same position that Haissaguerre do not disclose foot members that extend to one side of the elongate member. For the same reason as addressed above, the examiner maintains the Haissaguerre foot members may be considered to extend to one side of the elongate member and that the foot members may only be partially deployed to treat tissue having an apex (i.e. located in a space between the foot members). Applicant has not addressed why the prior art could not be combined, and the examiner maintains the obviousness rejections remain tenable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
November 20, 2009